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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/829,026	04/09/2001	Michael Fox	1662/52302	8407

26646 7590 01/14/2002

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ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/829,026

Applicant(s)

FOX ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Kreutter et al. (US 5,627,200).

Kreutter discloses a composition comprising β_3 -adrenoceptor antagonist or agonist (abstract, column 2, lines 12-18 and column 5, line 21), suitable pharmaceutical solid or liquid carrier or diluent to form capsules, tablets, powders, syrups, solutions and suspensions, additional optional components such as flavorants, sweeteners and excipients (column 19, lines 28-36), binders and disintegrants (column 19, lines 37-46), surfactants, sesame or peanut oil, ethanol, water or suitable mixtures thereof, N-methyl glucamine, polyvinylpyrrolidone and mixtures thereof (column 19, lines 60-66). The composition may also comprise HMG-CoA reductase inhibitor (lovastatin, simvastatin and pravastatin) and cholestyramine anion exchanger (column 26, lines 15-20). Kreutter discloses method for treating intestinal motility disorders, intestinal ulcerations, inflammatory bowel disease, ulcerative colitis, Crohn's disease and proctitis, and gastrointestinal ulcerations, depression, prostate disease and **dyslipidemia** by administering the said composition (abstract and column 2, lines 12-18). Future intended use is not critical in composition claims. Kreutter anticipates the claim.

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Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kreutter et al. (US 5,627,200).

The teaching of Kreutter is discussed above. Although, the generic claim of the invention broadly teaches a composition comprising an HMG-CoA reductase inhibitor, amino-group containing polymeric compound (cholestyramine) and amido group containing polymeric compound (polyvinylpyrrolidone), Kreutter is silent on the amounts the components of the composition. And determination of the ranges of the amounts of the components of the composition is within the purview of the skilled artisan and the scope of the broad range of components taught in the dependent claims may be encompassed in the prior art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Kreutter. One having ordinary skill in the art would have been motivated to prepare the composition of Kreutter and administer it to a person in need thereof to treat intestinal motility disorders, intestinal ulcerations, inflammatory bowel disease, ulcerative colitis, Crohn's disease and proctitis, and gastrointestinal ulcerations, depression, prostate disease and **dyslipidemia**. Determining the amounts of the parts of a composition is within the purview of

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the skilled artisan to do and therefore obvious absent evidence in unexpected results to the contrary.

5. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsujita et al. (US 5,627,375).

Tsujita discloses a composition comprising HMG-CoA reductase inhibitor (pravastatin, lovastatin, simvastatin, fluvastatin, rivastatin and atorvastatin), insulin sensitizers, vehicles, lubricants, binders, disintegrants and stabilizers (abstract, column 2, lines 28-46 and column 5, line 42 to column 6 line 12). The composition is formulated as tablets, capsules, granules, powders, syrups, injections (intravenous, intramuscular or subcutaneous for parenteral administration), suppositories and ointments (column 5, lines 30-36). Pharmaceutically acceptable vehicles are lactose, sucrose, mannitol, sorbitol, starch and starch derivatives, cellulose and cellulose derivatives (column 5, lines 42-55). Lubricants are magnesium stearate, calcium stearate, waxes and colloidal silica (column 5, lines 56-64). Binders include polyvinylpyrrolidone and macrogol and the compounds listed under vehicles (column 5, lines 65-67). Disintegrants may be the same as mentioned under vehicles, chemically modified starches and celluloses and bridged polyvinylpyrrolidone (column 6, lines 1-5). Phenols, benzalkonium chloride and propylparaben are the optional stabilizers (column 6, lines 6-12).

Although Tsujita does not specifically include cholestyramine in said composition, the prior art nonetheless discloses by reference that pravastatin and cholestyramine-containing composition is well known composition for lowering lipoprotein levels (column 1, lines 38-41). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Tsujita. One having ordinary skill in the art would have been

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motivated to prepare the composition of Tsujita and incorporate cholestyramine since pravastatin and cholestyramine can be combined since Tsujita's composition of HMG-CoA reductase inhibitor and insulin sensitizers is reported to show synergistic effect and better at treating arteriosclerosis. Determining the amounts of the parts of a composition is within the purview of the skilled artisan to do and therefore obvious absent evidence in unexpected results to the contrary. The comprising language in the claims allows for other ingredients in the composition and future intended use is not critical in a composition claim.

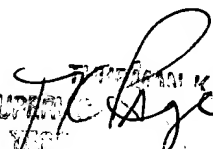
6. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
January 5, 2002


THURMAN K. PAGE
SUPERVISOR
703-308-2927
FEB 11 2002